UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEURONTIN MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	
THIS DOCUMENT RELATES TO: ALL MARKETING AND SALES PRACTICES ACTIONS	MDL Docket No. 1629 Master File No. 04-10981 Judge Patti B. Saris Mag. Judge Leo T. Sorokin

JOINT SURREPLY MEMORANDUM OF LAW OF THE CLASS AND COORDINATED PLAINTIFFS IN OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS

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The Class Plaintiffs (*Harden Manufacturing Corp., et al*. v. *Pfizer, Inc., et al*.) and the Coordinated Third Party Payer ("TPP") Plaintiffs (*The Guardian Life Insurance Company of America* v. *Pfizer, Inc*. and *Aetna, Inc*. v. *Pfizer, Inc.*) (collectively, "Plaintiffs") respectfully submit this joint surreply memorandum of law in opposition to defendants Pfizer, Inc. and Warner-Lambert Company's (collectively, "Defendants'") motions to dismiss the Amended Class Action Complaint ("Cl. Comp.") and the First Coordinated Amended Complaint ("Coord. Comp.," and, collectively, the "Complaints").

I. INTRODUCTION

To safeguard the health and safety of the general public, pharmaceutical manufacturers are required by law to speak fully and truthfully about the effectiveness and safety of their products for any uses that have not been scientifically proven effective -- and not to speak of such uses at all for any *commercial* purpose, but only in response to legitimate and unprovoked scientific inquiries. Defendants, for a commercial purpose, devised a complex scheme to avoid these laws, blessed at the highest corporate levels, putting the public health and safety at risk for financial gain. They have profited handsomely from this scheme, reaping billions of dollars a year from Neurontin sales for unapproved uses achieved by reason of their deceptive and unlawful promotional activities. Defendants have paid the debt they owed to the federal and state governments for this abuse of the public trust. These actions seek similar redress for the private victims of defendants' scheme.

II. PLAINTIFFS HAVE ALLEGED THAT DEFENDANTS COMMITTED FRAUD AND ACTED WITH SCIENTER

Defendants repeat their argument that Plaintiffs have not alleged that they knowingly engaged in any fraudulent conduct. One cannot help but wonder if Defendants have even read Plaintiffs' Complaints or opposition brief.

Plaintiffs allege that Defendants developed, at the highest corporate levels, a multi-faceted scheme to promote Neurontin as effective for the treatment of conditions for which it had not been approved, and for which there was no credible scientific evidence it was effective, for the express purpose of causing physicians to prescribe Neurontin for these unapproved and unproven uses. Plaintiffs have detailed that study after study – most of them sponsored by Defendants -- either failed to show that Neurontin was effective in treating these conditions, or concluded that it was *in*effective. *See* Cl. Comp. ¶¶ 118, 137-38, 144, 152, 164, 167, 169, 174-75; Coord. Comp. ¶¶ 108, 114-15, 122, 132. Plaintiffs further allege that Defendants sought to persuade researchers to alter their unfavorable conclusions, and, when these efforts failed, misrepresented those conclusions both to prescribing physicians and the compendia upon which they rely for objective, scientific information. *See* Cl. Comp. ¶¶ 118-121, 137-38, 144-46, 152-54, 164-65, 167-69, 174-76; Coord. Comp. ¶¶ 108-110, 114-17, 121-23, 131-32, 134-36.

Plaintiffs allege that notwithstanding this succession of scientific failures (most of which Defendants succeeded in keeping secret), Defendants -- through their partners in crime, the medical marketing firms -- sponsored hundreds[1] of medical "education" seminars and "consultant's meetings"[2] with groups of prescribing physicians, with the *sole purpose* of persuading them that Neurontin was the treatment of choice for a variety of unapproved and unproven uses. *See* Cl. Comp. ¶¶ 50-55, 63, 74-75, 81, 86, 89-90, 91, 104; Coord. Comp. ¶¶ 41-

[1] Discovery in the *Franklin* case was limited temporally to documents created before the end of 1998, over five years before Warner-Lambert's guilty plea, and geographically to only one of Parke-Davis' five regional customer business units ("CBUs"), the Northeast CBU. Accordingly, it is likely that the Complaints, which are based primarily on the discovery taken in *Franklin*, catalogue only a fraction of Defendants' unlawful and fraudulent promotional activities.

[2] Plaintiffs have alleged, with specificity, that the medical marketing firms had attendees sign sham consulting agreements so that Defendants could pay them for listening to the Neurontin sales pitch by Defendants' *own employees*, despite the fact that such "meetings" were and are forbidden by federal law. *See* Cl. Comp. ¶¶ 213-222.

42, 48, 60, 66, 70, 77, 94-95. Plaintiffs allege that Defendants hand-picked the physicians who spoke at these meetings, whom they rewarded with grants, honoraria, and luxury travel, to ensure that they would not deviate from Defendants' desired message. *See* Cl. Comp. ¶¶ 96-104; Coord. Comp. ¶¶ 87-95. Plaintiffs allege Defendants deliberately concealed from the attendees Defendants' clandestine role in orchestrating these affairs, in order to lull them into the false belief that they were receiving full and unbiased presentations from experts in their respective fields. *See* Cl. Comp. ¶¶ 42, 51, 53, 54-56, 74, 80, 89; Coord. Comp. ¶¶ 30, 34, 59-60, 66, 77. Plaintiffs allege that while presenting physicians privately shared among themselves serious doubts about the scientific basis for and ethics of their presentations, any presenter who had the audacity to present an unfavorable view of Neurontin *publicly* was "blacklisted" from speaking at any future events by the medical marketing firms, who begged forgiveness from Defendants for the infraction. Cl. Comp. ¶ 63; Coord. Comp. ¶ 49. The Neurontin Promotional Enterprise was a tightly run ship, and Defendants were firmly at its helm, reaping billions of dollars in sales and profits as a result of their unlawful and fraudulent marketing scheme.

Defendants cannot even muster a *pro forma* denial of these highly specific allegations, but argue, untethered to any relevant authority, that they cannot be penalized for their deceptive marketing campaign, and should be allowed to keep their ill-gotten gains, because they kept the physicians they selected to speak at these events ignorant of the true facts in Defendants' possession. *See, e.g.*, Reply Br. at 4 ("plaintiffs have not identified any contrary facts of which *the speakers were aware* when they made the alleged statements") (emphasis added). It is immaterial whether these physicians *consciously* misled their captive audiences, or were themselves dupes or pawns in Defendants' marketing campaign. Plaintiffs allege that *Defendants* intended to mislead these audiences, and that they were in fact misled into

prescribing Neurontin for the treatment of conditions for which it was unproven or ineffective. *See* Cl. Comp. ¶¶ 30, 34, 59-60, 66, 77; Coord. Comp. ¶¶ 51, 53, 54-56, 74, 80, 89. Plaintiffs allege enough to entitle them to discovery into what was said by the speakers at these meetings, the messages received by their audiences, the information provided to or withheld from them by Defendants, the prescribing behavior of the speakers and attendees, and the other matters bearing on Defendants' unlawful promotional scheme. Nothing more is before the Court at this time.

Remarkably, Defendants argue that they were free to promote their product with half-truths, and withhold unfavorable information, because the federal Food, Drug, and Cosmetic Act ("FDCA") does not impose any contrary "affirmative obligations," nor do the numerous professional guidelines governing the pharmaecutical industry "impose any duties." Reply Br. at 7. Defendants could not be more wrong. *See* 21 U.S.C. § 353 (defining a misbranded drug as one that's "labeling"[3] is 'false or misleading in any particular"), 21 U.S.C. § 321(n) (in determining whether an article or advertising is misbranded because it is misleading "there shall be taken into account (among other things) not only the representations made or suggested by statement, word, design, device or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in light of such misrepresentations or material"). *See also* 21 CFR § 202.1(e)(5)-(7) (prohibiting "prescription drug advertising[4]" which is false or misleading with regard to effectiveness; and prohibiting promotional material

[3] "Labeling" is a term of art in food and drug law and refers to any material that describes a prescription drug's properties, regardless of whether the material is actually part of a drug's label or package insert. *See V.E. Irons, Inc. v. United States*, 244 F.2d 34, 39 (1st Cir. 1957) (labeling includes "all literature used in the sale of food and drugs, whether or not it is shipped into interstate commerce"). *See also* 21 CFR 202.1(l)(2) (labeling includes brochures, booklets, slides, exhibits, and pieces of printed, audio or visual matter descriptive of a drug)

[4] Plaintiffs allege that the promotional events and literature relating to off-label use of Neurontin created by Defendants and their co-conspirators were promotional in nature and therefore constituted "prescription drug advertising" pursuant to 21 U.S.C. § 352(n). *See* Cl. Comp. ¶¶ 39-43; Coord. Comp. ¶¶ 23, 30-32.

which is "false, lacking in fair balance or otherwise misleading").

Professional guidelines rarely have the force of law, but the several cited by Plaintiffs are likewise sufficient to trigger a duty to disclose. *Bonilla v. Volvo Car Corp.*, 150 F.3d 62, 70 (1st Cir. 1998).[5] Plaintiffs have alleged that Defendants committed fraud.

III. PLAINTIFFS HAVE ALLEGED THAT DEFENDANTS CAUSED THEM INJURIES

A. Plaintiffs Have Alleged Proximate Cause

In *Franklin*, this Court held that the plaintiff had presented enough evidence that Defendants' misconduct proximately caused Neurontin prescriptions to be written (and paid for) for off-label uses to withstand a motion for summary judgment. *See* Opp. Br. at 12-13. *A fortiori*, Plaintiffs' allegations here — which are far more detailed than the allegations in *Franklin* — easily withstand a motion to dismiss.

Defendants dispose of this Court's carefully considered opinion in a mere footnote, arguing that "that case involved causation under the False Claims Act, not under RICO or state consumer fraud statutes." Reply Br. at 11 n.3. As this Court made clear in *Franklin*:

> Parke-Davis misstates the legal standard for causation. The FCA [False Claims Act] does not provide a special definition for causation, and neither the Supreme Court nor any Circuit Court of Appeals has grafted such a special definition on the FCA. Absent an FCA-specific definition of causation, *the Court will apply common-law tort causation concepts . . . .*

United States ex rel. Franklin v. Parke-Davis, 2003 WL 22048255, *11 (D. Mass. Aug. 22, 2003) (emphasis added). These same "common law tort causation concepts" apply to Plaintiffs'

[5] Defendants complain, in a footnote, that "one of the guidelines does not even purport to apply to anyone other than doctors." Reply Br. at 8 n.1. Parke-Davis enlisted its own physician-employees in its scheme to defraud. *See United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 45 (D. Mass. 2001) ("Parke-Davis's medical liaisons, including [Dr. Franklin], were instructed to make exaggerated or false claims concerning the safety and efficacy of [Neurontin] for off-label uses. . . . and to misrepresent their scientific credentials and to pose as research personnel").

claims here:

> In *Holmes*, 503 U.S. at 268, 112 S.Ct. 1311, the Supreme Court stated that a plaintiff's standing to sue under RICO requires "a showing that the defendant's violation not only was a 'but for' cause of his injury, but was the proximate cause as well." To determine in a given case whether proximate cause is present, *common law principles are applied*. *See id*. at 267-68, 112 S.Ct. 1311 (explaining that statutory standing under RICO encompasses common law principles of proximate cause because Congress implicitly incorporated those principles into the RICO statute).

Desiano v. Warner-Lambert Co., 326 F.3d 339, 348 (2d Cir. 2003) (emphasis added). *See also id*. at 348-49 ("New Jersey's common-law proximate cause requirements" applied to claims for violation of New Jersey Consumer Fraud Act ("NJCFA") and unjust enrichment). Defendants repeat their mantra that causation under RICO has a heightened pleading requirement, but ascribe no concrete meaning to this incantation, aside from their argument regarding *Laborers Local 17 Health & Benefit Fund v. Philip Morris, Inc.*, 191 F.3d 229 (2d Cir. 1999), addressed separately below.

Next, Defendants attempt to foist upon Plaintiffs a "fraud on the market" theory they have expressly disavowed (*see* Opp. Br. at 13 & n.13, 14), in order to set up a "straw man" Defendants might plausibly knock down. In a desperate bid to resuscitate the argument, Defendants substitute their own definition of the theory, which would include virtually any type of fraudulent marketing claim that might be asserted in connection with the sale of anything other than securities, for the far narrower "price inflation" theory expressly set forth in their cited cases (*see* Opp. Br. at 13-14 & n.13, 14), which also validate *Plaintiffs'* theory that "the sales would not have occurred absent the fraud . . . ." *Summit Properties Inc. v. Hoechst Celanese Corp.*, 214 F.3d 556, 560 (5th Cir. 2000). *Accord Desiano*, 326 F.3d at 349. Plaintiffs have alleged proximate cause.

B. TPPs Were Directly Injured by Defendants' Wrongful Conduct

In their opposition brief (at 14-16), Plaintiffs demonstrated the well-established standing of third-party payers to recover amounts they paid for prescription drugs as a result of deceptive marketing practices, citing *Desiano,* a case involving these same Defendants, and this Court's decision in *In Re Pharmaceutical Industry Average Wholesale Price Litigation* (*"AWP II"*) rejecting similar "causation" and "remoteness" arguments by Pfizer and its co-defendants as "'bordering on the frivolous.'" 307 F. Supp. 2d 196, 207 (D. Mass. 2004) (citation omitted).

In their Reply, Defendants renew the same argument, contending that *Desiano* did not involve the "more stringent" causation requirements under RICO and involved direct, as opposed to indirect, misrepresentations to the TPPs. Reply Br. at 12. These arguments grossly misconstrue *Desiano*, and recycle the same worn-out tobacco-case analogy that this Court and others have repeatedly rejected.

Desiano expressly held that TPPs were entitled to prosecute their claims "even assuming arguendo" that the RICO proximate cause standard (of *Laborers Local 17*) were applied. 326 F.3d at 348-50. As here, among the factual and legal reasons compelling that conclusion were the following: (a) "the excess money Plaintiffs paid Defendants for the Rezulin that they claim they would not have purchased 'but for' Defendants' fraud – were in no way 'derivative of damage to a third party" (*id.* at 349 (footnote omitted)); (b) "each [TPP] and its patient has its own, segregable, claim for economic harm" (*id.* at 350); (c) TPPs, "as 90 percent co-payers, are the parties with the largest direct economic injury" (*id.*); and (d) numerous courts, in a "variety of contexts", have held that TPPs are buyers entitled to sue (*id.* (citations omitted)).[6]

[6] The Second Circuit is by no means an "outlier" court on this issue. *See, e.g., In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 531 (3d Cir. 2004) (rejecting claim that TPPs have no standing to assert, *inter alia*, GBL § 349 claims for overpriced drugs due to false and misleading statements made by manufacturer; citing *Desiano* with approval: "TPPs are . . . purchasers"); *In*

Similarly misplaced is Defendants' contention that TPPs may not recover because "doctors, not the [TPPs] or the public, were the recipients of the alleged misstatements." Reply Br. at 12. In *AWP II*, this Court rejected a virtually identical argument by Pfizer, because "[i]n the private, end-payor context, the harm alleged by Defendants' alleged actions is visited directly upon the end-payor Plaintiffs, as they have paid directly for the named drugs based on the AWP's." 307 F. Supp. 2d at 207. *See also Franklin*, 147 F. Supp. 2d at 52-53 (rejecting Defendants' argument that government's damages were too remote because "the independent actions of the physicians who wrote the off-label prescriptions . . . were an intervening force that breaks the chain of legal causation"). This same reasoning compels permitting TPPs to recover the damages they have sustained as a result of Defendants' wrongful scheme.

The Coordinated Plaintiffs further allege that Defendants knew that "the substantial drug sales that Defendants sought were dependent upon third-party payers, such as Plaintiffs, covering the cost of the drug or purchasing and dispensing the drug to plan members." Coord. Comp. ¶ 2. Defendants knew that their ability to get pharmacy directors to authorize the inclusion of Neurontin on formularies without restriction was critical to its commercial success.

Moreover, Defendants are incorrect in arguing that their misrepresentations were made *only* to doctors. The Complaints do not so allege: they state that Defendants knowingly published "articles, studies and reports misrepresenting the scientific credibility of data and the authors of the articles, studies and reports." *Id.* ¶ 3; *see also* Cl. Comp. ¶ 115. Discovery will

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re Terazosin Hydrochloride Antitrust Litig., 220 F.R.D. 672 (S.D. Fla. 2004) (certifying 17-state class of TPPs and consumers to pursue overcharge litigation against pharmaceutical manufacturer over defendants objections that the TPPs "pass on" all damages through premium collection); *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326 (E.D. Mich. 2001) (certifying class including TPPs on recognition that TPPs pay a portion of the retail price of prescription drugs); *In re Lupron Mktg. & Sales Litig.*, __ F.R.D. __, 2005 WL 1140553, *20 (D. Mass. May 12, 2005) (approving settlement including TPPs, remarking that they account for the "lion's share" of damages due to overpriced pharmaceutical product Lupron).

reveal that these studies were reproduced and provided to formulary decision-makers employed by TPPs across the country.[7] Defendants have sufficient notice to understand that they are being sued by TPPs both for the false information Defendants disseminated throughout the country, as well as for the false statements made directly to TPPs by Warner Lambert's "NAMs" to achieve formulary access for Neurontin.

IV. PLAINTIFFS HAVE ALLEGED COGNIZABLE INJURIES

Plaintiffs have alleged a cognizable injury, first by alleging that Neurontin is ineffective for treating off-label conditions, and second by alleging that plaintiffs paid for a drug they would not have paid for had it not been for Defendants' misrepresentations. In their reply brief, Defendants simply rehash the same arguments offered in their moving papers.

First, with regard to allegations of inefficacy, Defendants concede that the Class Complaint makes a general allegation that Neurontin is ineffective for the off-label uses for which it is prescribed (*see* Reply Br. at 13, citing Class Comp. ¶ 249), but claim that the Coordinated Complaint does not contain such an allegation. However, Defendants simply gloss over the allegation in the Coordinated Complaint, virtually identical to that in the Class Complaint, that "[t]he fraudulent scheme was designed to, and did, cause Plaintiffs to pay for Neurontin prescriptions to treat conditions for which the drug is not proven to be medically safe, efficacious, effective or useful." *See* Coord. Comp. ¶ 183.

Defendants also ignore the other detailed allegations in the Complaints regarding the inefficacy of Neurontin for each off-label condition, and instead make the baseless claim that Plaintiffs have not alleged any specific facts to support the allegation that Neurontin is

[7] In addition, discovery will reveal that during the relevant period, Mr. George Cavic headed a division at Warner Lambert called "Health Care Management," which employed a staff of approximately 100 "National Account Managers," or "NAMs," whose sole responsibility was to market pharmaceutical products, including Neurontin, to TPPs.

ineffective. *See* Opp. Br. at 6 n.2, 16; Class Comp. ¶¶ 152, 156, 164, 197, 209, 238; Coord. Comp. ¶¶ 103, 110-11, 113, 121, 127, 133-35, 139. For example, Defendants ignore the specific allegations concerning Defendants' knowledge of clinical trial evidence which established that Neurontin was not significantly superior to a placebo in treating bipolar disorder. *See* Class Comp. ¶ 152. Instead, Defendants point to the length of time that the individual plaintiffs took Neurontin and then ask this Court simply to infer that Neurontin was effective for them. Not only is such an argument a factual stretch, it is wholly inappropriate in connection with this motion. *See Alternative Energy, Inc. v. St. Paul Fire and Marine Ins. Co.*, 267 F.3d 30, 33 (1st Cir. 2001) (stating the well-established rule that "in ruling on a motion to dismiss, a court must . . . construe all reasonable inferences in favor of the plaintiffs"). Therefore, based on the numerous allegations in both Complaints that Neurontin is ineffective, this argument must fail.[8]

Second, Defendants again try to analogize the allegations here to pharmaceutical cases in which courts have dismissed claims alleging economic loss on the part of plaintiffs who bought a drug that physically injured others. *Rivera v. Wyeth-Aherst Laboratories*, 283 F.3d 315 (5th Cir. 2002), a case cited by Defendants, summarizes those claims as follows: "Wyeth sold Duract; Rivera purchased and used Duract; Wyeth did not list enough warnings on Duract, and/or Duract was defective; other patients were injured by Duract; Rivera would like her money back." *See* 283 F.3d at 319. Plaintiffs here have alleged something quite different: Defendants sold Neurontin; Defendants provided inaccurate and misleading information regarding the efficacy of Neurontin for certain off-label conditions; Plaintiffs purchased and (in the case of the patients) used Neurontin for an off-label use; Plaintiffs would not have purchased Neurontin for this off-

[8] As Plaintiffs noted in their opposition, while Plaintiffs have alleged that Neurontin is ineffective for unapproved uses, their claims do not depend on proof of that fact. Rather, it is the *absence* of scientific evidence that Neurontin is effective for unapproved uses that renders Defendants' claims of effectiveness misleading and actionable.

label use if Defendants had not fraudulently misrepresented its efficacy; Plaintiffs seek damages based on their purchases. These claims are not derivative of an injury to someone else, as were the claims in *Rivera* and *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171 (D.C. Cir. 2003).[9] *Desiano* is on all fours: "Plaintiffs allege an injury directly to themselves; an injury, moreover, that is unaffected by whether any given patient who ingested Rezulin became ill. Plaintiffs' claim is that the Defendants' wrongful action was their misrepresentation of Rezulin's safety, and that this fraud directly caused economic loss to them as purchasers." 326 F.3d at 349. In *Rivera*, the Fifth Circuit stated that Rivera "paid for an effective pain killer, and she received just that—the benefit of her bargain. . . Duract worked. Had Wyeth provided additional warnings or made Duract safer, the plaintiffs would be in the same position they occupy now." 283 F.3d at 320. As alleged in the Complaints here, Plaintiffs would *not* be in the same position if Defendants had not fraudulently promoted off-label uses of Neurontin.

Defendants attempt to distinguish *Desiano* based on the fact that Plaintiffs here have not alleged that they would have bought an equally effective, cheaper alternative. To be sure, Neurontin is an unusually expensive drug, a fact Plaintiffs could easily allege. However, this argument goes to the proper *measure* of damages, rather than the existence of an injury. The injuries alleged in *Desiano* are the same type alleged here: the purchase of a drug based on misrepresentations by Defendants. *See* 326 F.3d at 339 ("Plaintiffs assert that members of the class paid approximately $1.4 billion to purchase the drug. . . . In their complaint, plaintiffs sought to recover the moneys they spent purchasing Rezulin.").

Finally, Defendants again raise the red herring that the TPPs are barred from claiming

[9] In addition, *Williams* is a self-described "'fraud on the market' theory" case (297 F. Supp. 2d at 177), in which plaintiffs "alleged injury is a higher price for Oxycontin because of defendants' promotional tactics." *Id.*

harm because, under a number of statutes, they are required to reimburse off-label prescriptions. This argument is without merit. The TPPs paid many millions of dollars for off-label prescriptions that would not have been written, if not for Defendants' fraud. The fact that TPPs fulfilled their statutory obligations does not negate the fact that the TPPs were the primary victims of Defendants' misconduct. Plaintiffs have alleged cognizable injuries.

V. PLAINTIFFS ADEQUATELY ALLEGE RICO CLAIMS

Defendants' Reply treads the same ground as Defendants' Motion in claiming that Plaintiffs have failed to adequately allege RICO claims because Plaintiffs 1) fail to adequately allege a RICO association-in-fact, 2) fail to adequately allege that Defendants had control over the RICO enterprises alleged, and 3) fail to allege sufficient predicate acts by Defendants. Defendants are still wrong on each of these counts.

A. Plaintiffs Have Alleged Associations-in-Fact

Defendants argue that Plaintiffs have failed to plead that each of the participants in the associations-in-fact knew of the fraudulent nature of the enterprise. Reply Br. at 15-16. In response, Plaintiffs have demonstrated that the Complaints do sufficiently allege that each of the participants actively and knowingly participated in Defendants' scheme. Opp. Br. at 20-21. Plaintiffs will not re-plow the same ground here.

Moreover, an association-in-fact does not require that each of the participants know of the fraud. It simply requires that an association-in-fact be used by one or some of its participants to achieve unlawful ends. "Since the association-in-fact itself can be completely innocent . . . we see no reason to assume that it cannot be constituted of individuals, apart from one or a few RICO violators, who are totally innocent of wrongdoing." *Rodriguez v. Banco Central*, 777 F. Supp. 1043, 1055 (D.P.R. 1991).

Requiring that every associate know the nature of the fraud is inconsistent with the very

purpose and underpinnings of the RICO statute and would preclude the use of RICO against those who infiltrate an otherwise innocent and legitimate business. 18 U.S.C. § 1962 was "intended to punish the person who conducts the affairs of an otherwise legitimate business in an illegal manner." *Yellow Bus Lines, Inc. v. Drivers, Chauffeurs & Helpers Local Union 639*, 883 F.2d 132, 138 (D.C. Cir 1989).

The argument that each participant must know of the fraud in order to be part of an association-in-fact is akin to stating that an association-in-fact must also be "an association of wrongdoers." This contention has been rejected. *See Rodriguez*, 777 F.Supp. at 1055-56 ("A plaintiff could conceivably prove an association-in-fact that is completely legitimate except for the fact that one of its associates is using the entity, even perhaps without the knowledge of any other associates, for the purpose of engaging in the RICO predicate pattern. . .).

The case of *Crowe v. Henry*, 43 F.3d 198 (5th Cir. 1995) is instructive on this point. The plaintiff in *Crowe* claimed an association-in-fact between himself and the defendant, who together bought and developed farmland. The plaintiff sued the defendant, his lawyer, and his law firm, under RICO. The Court held that the plaintiff alleged a valid association-in-fact consisting of himself and the defendant, even though the plaintiff obviously had no knowledge of the fraudulent acts committed by the defendant. *Crowe*, 43 F. 3d at 205.

In order to be liable under RICO a defendant has to commit some wrong, but even the defendant does not have to know everything about the overall conspiracy. *See, e.g., United States v Church*, 955 F.2d 688, 694 (11th Cir. 1992):

> Church claims that he was ignorant of the overall RICO conspiracy and thus did not agree to join the conspiracy in violation of 18 U.S.C. § 1962(d). Agreement to participate in a RICO conspiracy, however, can be proved in either one of two ways: (1) by showing an "agreement on an overall objective," *United States v. Valera*, 845 F.2d 923, 929 (11th Cir. 1988), *cert. denied*, 490 U.S. 1046, 109 S. Ct. 1953, 104 L. Ed. 2d 422 (1989); or (2) in the absence of an agreement on an

> overall objective, by showing that a defendant agreed personally to commit two predicate acts and therefore to participate in a "single objective" conspiracy.

Defendants also attack the associations-in-fact pled by Plaintiffs on the grounds that the Complaints fail to show that participants shared a common purpose. However, the Complaints clearly allege that the participants sought to promote Neurontin for off-label purposes. That was the common purpose of each of the participants, in addition to reaping profit. Opp. Br. at 21. Defendants, the doctors, and the vendors involved each had a vested interest in spreading the word about Neurontin's many off-label uses. Physicians received payment for lending their name to articles that, in addition to bringing them easy money, would add to their professional credentials. *See* Cl. Comp. ¶¶ 53, 98, 100-104, 108, 111-112; Coord. Comp. ¶¶ 35, 65, 78, 79-80, 84-85, 93, 95. The vendors had similar motives. The greater the success of their campaign to promote Neurontin for off-label uses, the stronger their relationship with Defendants, the more events or articles they would be hired to produce, and the greater profit they could reap. *See* Cl. Compl. ¶¶ 44, 48-49, 53-57, 78-80,89, 108-114; Coord. Comp. ¶¶ 30, 31, 34, 40-44, 83-86, 89-92, 94, 96-98, 117.

Defendants also fail to adequately distinguish the holding of *In re Managed Care Litig.*, 185 F. Supp. 2d 1310 (S.D. Fla. 2002), claiming that the Court's holding was dependent upon the participants of the enterprise having "celebrated" their network of healthcare providers. However, the point of *Managed Care* was the Court's rejection of defendant's argument that a RICO enterprise requires a structure "beyond that commonly found in on-going contractual relationships." It does not. Accordingly, Defendants are mistaken in their assertion that the contractual relationships among the participants in the enterprises were merely legitimate business interactions that cannot give rise to an association-in-fact for RICO purposes.

B. Plaintiffs Have Alleged That Defendants Controlled the Enterprises

Defendants repeat their contention that Plaintiffs' allegations concerning Defendant's control over the Enterprises are not specific enough. Reply at 19. However, the Complaints detail exactly how Defendants controlled the content of the seminars, presentations, articles, and studies, (Cl. Comp. ¶¶ 29-31, 39, 49, 63, 105, 108-110, 121, 123; Coord. Comp. ¶¶ 28, 30-37, 39, 49-51, 59-61, 63-65, 72, 75-78), how Defendants controlled to whom the content would be directed, (Cl. Comp. ¶¶ 42-45,43-45,52,105; Coord. Comp. ¶¶ 28, 30-37, 48, 68, 67) and how Defendants controlled how and by whom the content would be provided (Cl. Comp. ¶¶ 42-45,50-58,63,98,105; Coord. Comp. ¶¶ 28, 30-37, 41-43, 45, 55-56, 59-61, 63-65, 68, 70, 89-92). There is nothing of consequence the Defendants did not control. *See* Opp. Br. at 23 n.27.

Defendants claim that the only purported example of control in the Class Complaint actually shows control by a vendor and not Defendants. *See* Reply Br. at 19. Examination of that paragraph shows that Defendants were very much in control. Paragraph 63 of the Class Complaint explains how Cline Davis and Parke-Davis had discovered that one of their presenting physicians might describe negative results, and that Cline Davis took steps to plant a shill in the audience to ask directed questions in order to counteract any negative information. Cline Davis then "assured Parke-Davis that 'guidelines have been set to ensure that this type of situation [a negative presentation] does not happen again." Cl. Comp. ¶ 63. Clearly, Parke-Davis was in control, as evidenced by the fact that the vendor was required to report back to Defendants on exactly how it would conduct all future searches for speakers.

C. Plaintiffs Have Sufficiently Alleged Predicate Acts

In their Reply, Defendants deny that they have ignored the thousands of instances of mail and wire fraud alleged in the Complaints by stating "this plainly is not the case." Reply at 20. This denial adds no more to Defendants' argument than the single sentence in their opening brief

that summarily dismisses Plaintiffs' allegations of mail and wire fraud. Opening Br. at 22. In fact, thousands of instances of mail and wire fraud are pled in the Complaints. *See, e.g.*, Cl. Comp. ¶¶ 250-52; Coord. Comp. ¶¶ 184-86.

Defendants again concentrate only on the adequacy of the predicate acts of bribery alleged in the Complaints. Even on this matter they have missed the mark considerably. Defendants claim that Plaintiffs failed to allege that Defendants paid physicians in exchange for an agreement to 1) make positive statement about Neurontin, or 2) increase their prescription of Neurontin. Reply Br. at 20. However, this is exactly what is alleged. *See e.g.*, Cl. Comp. ¶ 287. "Defendants' acts consisted of, *inter alia*,: (a) paying substantial fees and extensive travel benefits to physician participants for agreeing to engage in peer-to-peer marketing; (b) paying physicians for studies that had minimal, if any scientific value or paying physicians to use their names on ghost-written articles; and (c) making outright payments, in the form of grants, to reward doctors who actively prescribed Neurontin or promoted it for off-label use." *Id.*

VI. PLAINTIFFS HAVE ALLEGED CLAIMS UNDER THE VARIOUS CONSUMER FRAUD STATUTES

A. TPPs Are "Persons" Entitled to the Protections of the NJCFA

In their Opposition Brief (at pages 24-25), Plaintiffs demonstrated that third-party payers are "persons" with standing to sue under the NJCFA. The NJCFA expressly defines "person" as "any" partnership, corporation, company, trust, business entity or association, in addition to natural persons and their legal representatives. N.J.S.A. 56:8-1(d).

The Act has been applied to cover the claims of commercial entities in business disputes in a variety of contexts, including a recent case involving claims by TPPs to recover from Merck for payments made to buy the prescription drug, Vioxx (*International Union of Operating Engineers Local 69 v. Merck, Inc.*, No. ATL-L-3015-04 (N.J. Super. Ct. Atl. Cty. July 8 2004)

(Pl. Ex. 3)), and the sale of a franchise (*Kavky v. Herbalife International of America*, 820 A.2d 677 (N.J. Super. Ct. App. Div. 2003)). Defendants simply argue that these two decisions were wrongly decided because the "NJCFA was never meant to apply to sophisticated institutions engaging in business transactions." Reply Br. at 21.

It is respectfully submitted that the New Jersey courts are better at interpreting their own state's statutes than self-interested defendants. Moreover, the analyses by the Courts in *Kavky* and *Local 69* are sound. As the Court in *Local 69* accurately observed in rejecting the very types of arguments advanced by Defendants here: (a) the CFA "uses the word 'person' not 'consumer'" (*Local 69* at 7), a distinction Defendants repeatedly ignore; (b) "the word 'person' is not limited to ... those who purchase personal or household items" (*id.*); (c) unlike the CFA, some consumer-oriented Acts in the State expressly "limit the definition of a 'consumer' to an individual" (*id.* at 7-8); (d) the TPPs "suffered an ascertainable loss by paying for a retail product based on false advertising and 'sharp practices' of the defendant" (*id.* at 8); and (e) "[i]f, for example, a 'person' buys a gift for a third party based on false advertising, it does not matter that the person who is duped into making the purchase does not personally use the product (*id.* at 10-11). *Each* of these reasons confirms that the Coordinated Plaintiffs are "persons" entitled to redress under the CFA.

B. The NJCFA and UCL May Be Applied to the Claims of Non-Residents

At the first case management conference in this MDL proceeding, Judge Saris informed the parties – *twice* -- that the Court would *not* decide choice of law issues on motions to dismiss.[10] Unwilling to accept the Court's admonishment, which lies well within its delegated

[10] Plaintiffs have requested the Reporter's Transcript of this November 23, 2004 case management conference, so that the Magistrate Judge to whom this motion has been referred can review Judge Saris' statements on the record, but Plaintiffs have been informed by the court reporter that it has not yet been transcribed and that the file may have been wiped out as a result

authority to manage these cases (*see* Opp. at 26 & n.32), Defendants insist that the Court do exactly that, claiming, incredibly, that "it should be clear that defendants are not asking the Court to make a choice of law decision . . . ." Reply Br. at 25. That is *exactly* what Defendants are asking the Court to do – rule that a single state's law may not be applied to the claims of nonresidents, and that the laws of all 50 states must therefore be applied.

In support of their untimely argument, Defendants contend that "California law embodies a strong presumption against extraterritorial application of its laws, particularly the UCL." Reply Br. at 23-24. In fact, in a UCL case, the California Supreme Court expressly *rejected* the argument that

> the law of the other states in which class members reside should presumably govern their claims unless the proponent of class certification affirmatively demonstrates that California law is more properly applied. To support this position, amici curiae point out that nationwide class actions may be, and often are, used to resolve the claims of nonresidents who lack the minimum contacts in the forum state normally needed to support personal jurisdiction. (*See Phillips Petroleum Co. v. Shutts, supra*, 472 U.S. at pp. 806 814, 105 S.Ct. 2965.) In such cases, they argue, California may not constitutionally weigh the scales in favor of applying its own law. We disagree.
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> As amici curiae acknowledge, and as already noted above, a forum state may constitutionally apply its own law to the claims of nonresident class members if the state has a " 'significant contact or significant aggregation of contacts' to the claims asserted by each member of the plaintiff class, contacts 'creating state interests,' in order to ensure that the choice of [the forum's] law is not arbitrary or unfair." (*Phillips Petroleum Co. v. Shutts, supra*, 472 U.S. at pp. 821-822, 105 S.Ct. 2965.) Accordingly, so long as the requisite significant contacts to California exist, a showing that is properly borne by the class action proponent, California may constitutionally require the other side to shoulder the burden of demonstrating that foreign law, rather than California law, should apply to class claims.

Washington Mutual Bank, FA v. Superior Court, 24 Cal. 4th 906, 920-21, 103 Cal.Rptr.2d 320,

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of a computer malfunction. Defendants do not deny that these directions were in fact given by the Court (*see* Opp. Br. at 26 ("As the Court cautioned the parties at the initial status conference, this battle is premature")), and implicitly acknowledge them in their argument. *See* Reply Br. at 25 (protesting that "defendants are not asking the Court to render a choice of law decision").

331 (Cal. 2001).[11]

Defendants reluctantly acknowledge that as long as the *Shutts* test is satisfied, a single state's law *may* be applied to the claims of a nationwide class, but argue that the NJCFA cannot be so applied here, because the only relevant "contact" with New Jersey is "the fact that Warner-Lambert was once headquartered" there. Reply Br. at 24. Class Plaintiffs have alleged far more than that; they have alleged that Defendants' fraudulent scheme was corporate policy, conceived and directed by high-level employees at Warner-Lambert's corporate headquarters (*see, e.g.*, Cl. Comp. ¶¶ 21-31, 254; Coord. Comp. ¶¶ 19-25), bringing the case squarely within the authorities relied upon by Plaintiffs, and distinguishing it from the cases cited by Defendants.[12]

In any event, as the Court has already determined *sua sponte*, the choice of law question is another battle, to be fought another day.

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[11] Contrary to Defendants' assumption, the Coordinated Plaintiffs' Tenth Claim for Relief, for violations of the UCL, is not asserted with respect to *all* of their Neurontin purchases, but only with respect to purchases made by or on behalf of their California insureds. Accordingly, this claim does not run afoul of *Norwest Mortgage, Inc. v. Superior Court*, 85 Cal. Rptr. 2d 18 (Ct. App. 1999), which holds that the *Shutts* test is not satisfied where "the only contact between the claims of [nonresident class] members and California is [the defendant's] state of incorporation." *Id*. at 26.

[12] *See also National Notary Ass'n v. U.S. Notary*, 2002 WL 1265555 (Cal. Ct. App. 2002) (distinguishing *Norwest Mortgage* where "the management decisions to commit the wrongful conduct" occurred in California) (although Rule 977(a) of the California Rules of Court provides that unpublished opinions are not citable in California courts, Defendants have cited an unpublished opinion in support of their contrary argument, *Shaw Indus., Inc. v. Superior Court*, No. B167878, 2003 WL 22995267 (Cal. Ct. App. Dec. 22, 2003)); *Boyes v. Greenwich Boat Works*, 27 F. Supp. 2d 543, 547 (D. N.J. 1998) (applying NJCFA to claim brought by Pennsylvania resident, because "this state has a powerful incentive to insure that local merchants deal fairly with citizens of other states"); *Gantes v. Kason Corp.*, 679 A.2d 106, 111-112 (N.J. 1996) (holding that there was a substantial state interest in deterring unlawful conduct and protecting the public against the distribution of unsafe products manufactured in New Jersey, even though the product was not purchased in New Jersey and the injury did not occur in New Jersey); *Peterson v. BASF Corp.*, 618 N.W.2d 821, (Minn. Ct. App. 2001) (affirming certification of a nationwide class action by farmers who were misled by defendant's conduct pursuant to the NJCFA).

C. The Coordinated TPPs Sufficiently State Claims Under the Remaining Deceptive Practice Statutes

Defendants' challenge to the sufficiency of the Coordinated Plaintiffs' claims for violation of the deceptive practice statutes of the remaining jurisdictions is meritless. As detailed in the Coordinated Complaint, these TPPs paid millions of dollars for illegitimate off-label uses of Neurontin in every state in the United States, the District of Columbia and the Commonwealth of Puerto Rico as a result of Defendants' fraudulent acts. Coord. Comp. ¶¶ 5-9, 188. These allegations, coupled with the detailed allegations concerning the wrongful scheme,[13] certainly provide "the facts necessary to state a claim" under the statutes and appropriately allege a "nexus" between the wrongful conduct and the statutes at issue. Reply Br. at 26.[14]

It is well settled that the deceptive practice statutes prohibit the making of false or misleading representations to the public. These statutes are broadly written and liberally construed in order to eradicate all forms of unfair and deceptive acts and practices.[15] *See National Consumer Law Center*, Unfair and Deceptive Acts and Practices § 4.2.3.1 (5th ed. 2001).

Moreover, as noted in Plaintiffs' opposition brief, Defendants' arguments are premature

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[13] *See, e.g.*, Coord. Comp. ¶¶ 2-4, 17-175, 182-183, 188, 309-12.

[14] The Coordinated Complaint is also replete with allegations that through deception, fraud and misrepresentations Defendants implemented a broad-based, national campaign to promote and sell Neurontin to treat conditions for which it was not proven to be medically safe, effective and useful. *See* Coord. Comp. ¶¶ 2, 3, 17, 23, 28-32, 34, 37-39, 41, 87, 102-68, 309. Plaintiffs further allege throughout the Coordinated Complaint that Defendants' unfair and deceptive acts were specifically designed to induce Plaintiffs to pay for Neurontin for off-label and non-medically safe and effective uses. *Id.* ¶¶ 170, 182, 183, 310, 312.

[15] *See, e.g., Veranda Beach Club v. Western Surety Co.*, 936 F.2d 1364, 1385 (1st Cir. 1991) (noting "broad impact" of Mass. Gen. L. Ch. 93A); *Ray v. Ponca/Universal Holdings, Inc.*, 22 Kan. App. 2d 47, 49, 913 P.2d 209, 212 (App. 1995) (noting liberal construction of the Kansas deceptive practices act); *Truex v. Ocean Dodge, Inc.*, 219 N.J. Super. 44, 49, 529 A.2d 1017, 1020 (App. Div. 1987) ("The [NJCFA] is broadly designed to protect the public, even when a merchant acts in good faith. We must read its remedial provisions with that purpose in mind").

and erroneous. Opp. Br. at 26, n.33. In *AWP*, this Court decided not to delve into the merits of the multiple state law claims at the motion to dismiss stage because challenges to these claims were "briefed inadequately," and "resolution [of these claims would] not affect the scope of the litigation." *See AWP II*, 307 F. Supp. 2d at 211 (class complaint); *In Re Pharmaceutical Industry Average Wholesale Price Litigation ("AWP")*, 339 F. Supp. 2d 165, 183 (D. Mass. 2004) (County of Suffolk complaint). The same reasoning applies here. Defendants' challenge to the claims is at best cursory and the scope of the litigation will not be affected if less than all of the state deceptive practice statutes are found to be applicable to Defendants' wrongdoing.

VII. DEFENDANTS' DECEPTIVE MARKETING PRACTICES ARE NOT PROTECTED BY THE FIRST AMENDMENT

Defendants' First Amendment argument is yet another red herring, intended to divert attention from unquestionably unprotected conduct by invoking irrelevant constitutional doctrines. The First Amendment does not protect fraud or other forms of public deception. *Illinois ex. rel. Madigan v. Telemarketing Associates, Inc.*, 538 U.S. 600, 612 (2003), *Donaldson v. Read Magazine, Inc.*, 333 U.S. 178, 190 (1948). Nor is there any constitutional protection for commercial speech that is misleading or concerns unlawful activity.[16] *Greater New Orleans Broadcasting Ass'n v. United States*, 527 U.S. 173, 183 (1999); *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557, 563 (1980). Consequently, there can be no First Amendment concerns for any of the Plaintiffs' claims that are premised on fraud or misrepresentation. When Plaintiffs prove the elements of these well-established

[16] Defendants' reply memorandum does not, and could not, contest Plaintiffs' position that the speech involved in this case is commercial, as opposed to scientific. Defendants' efforts to publicize Neurontin's use for unapproved indications was promotional speech designed to increase sales of the drug. Speech which is primarily related to the economic interests of the speaker and the audience is "commercial speech." *Central Hudson Gas & Electric Corp. v. Public Service Comm. Of New York*, 447 U.S. 557, 561 (1980).

common law and statutory causes of action, they will have also established that the misconduct meriting compensation is not protected by the First Amendment.

Only if Plaintiffs seek to impose liability for claims not based on the Defendants' dissemination of false or misleading information could a First Amendment defense possibly exist. But nowhere in Defendants' two oversized memoranda have Defendants identified such a claim.[17] Defendants devote pages to arguing that physicians' communication of information concerning the off-label use prescription drugs should be protected by the Constitution, but ignore the fact that none of Plaintiffs' claims are premised solely on such conduct.[18] All of Plaintiffs' claims require proof that Defendants engaged in recognized misconduct in addition to off-label promotion–such as fraud, misrepresentation, deception or bribery. Defendants' constitutional argument is addressed to an imaginary cause of action which Plaintiffs simply have not brought.

Defendants hypothesize that Plaintiffs must have brought such an innominate claim because they do not believe Plaintiffs have satisfied the pleading requirements for misrepresentation-based claims. To the contrary, all of Plaintiffs' causes of action are well established, and Defendants have failed to cite a single case holding that such claims may result in an unconstitutional imposition of liability.

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[17] The only claim that is not premised upon Defendants' misleading physicians about the benefits of Neurontin is the Class Plaintiffs' alternative RICO claim based upon predicate acts of commercial bribery. *See* Cl. Comp., ¶¶ 210-33. However, bribery is no more protected by the First Amendment than fraud. *Cf. United States v. Goldberg*, 906 F. Supp. 58, 64 (D. Mass. 1995) (providing illegal gratuities to politicians to influence legislation or executive decisions is not protected conduct under the First Amendment).

[18] Defendants' argument about the protected nature of communications between physicians regarding off-label usage ignores at least two other pertinent facts. First, Plaintiffs are not suing any physicians, and therefore the Complaint does not seek to impose any liability on physicians for this allegedly protected conduct. Second, Defendants do not have standing to raise the physicians' constitutional defense.

Thus, there is no need to engage in an analysis of whether the imposition of fraud, RICO, consumer protection or unjust enrichment liability is sufficiently tailored to protect substantial governmental interests without unduly impinging on protected speech, the analysis that is usually applied to cases where protected commercial speech may be at risk. As noted, there is no protected speech at issue here. But even if there were, imposition of civil liability in accordance with the elements of these well defined torts is clearly narrowly tailored to achieve the substantial governmental interest of protecting the health and welfare of citizens. Application of the standard rules of tort liability will insure that Defendants will only be penalized for misconduct that has caused injury to Plaintiffs, a burden that does not infringe any legitimate constitutional rights.

Finally, Defendants make the frivolous argument that holding them liable for materially misleading omissions is the equivalent of compelled speech. Imposing liability for failing to disclose material facts required to be disclosed by state or federal law is not a violation of the First Amendment. To rule otherwise would mean that half-truths, materially incomplete or deceptive statements and other recognized forms of deceptive business practices could never be punished. Simply stated, there is no principled reason for holding that the Constitution only permits the imposition of fraud or misrepresentation liability in cases of outright lies.

VIII. THE FDCA DOES NOT PREEMPT PLAINTIFFS' CLAIMS

In its opinion in *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, 321 F. Supp. 2d 187, 197-200 (D. Mass. 2004) ("*AWP IV*") this Court succinctly set forth the framework for analyzing claims of implied preemption of state law claims due to an alleged statutory conflict, such as the one asserted by the Defendants here. Defendants' reply memorandum once again ignores the guidance provided by the Court in its earlier

pharmaceutical litigation opinions[19] and, not surprisingly, arrives at the wrong conclusion.

A principal source of Defendants' error is their refusal to acknowledge that the Court must start its analysis with the strong presumption that Plaintiffs' state law claims are not preempted. *AWP IV* concisely describes when the presumption is applied and when it is not:

> The Courts have long presumed that the historic police powers of the states were not to be pre empted by a federal statute unless that was "the clear and manifest purpose of Congress." Medtronic, Inc. v. Lohr, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (citations omitted). The Supreme Court has established three primary lines of doctrine on the question of the presumption against preemption. First, as the Defendants state, "fraud on the agency" claims are generally not entitled to a presumption against preemption, for "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." Buckman [Co. v. Plaintiffs' Legal Comm., 531 U.S. 341] at 347, 121 S.Ct. 1012. See also Nathan Kimmel, Inc. v. DowElanco, 275 F.3d 1199, 1205 (9th Cir. 2002) . . .
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> Second, "[w]hen Congress legislates in a field which the States have traditionally occupied, like medical fee regulation, 'courts must presume that Congress has not preempted state power to act unless that was Congress's "clear and manifest purpose." ' " [AWP I], 263 F.Supp.2d at 187 (quoting Mass. Med. Soc'y, 815 F.2d at 791 (citation omitted)). See also Medtronic, 518 U.S. at 485, 116 S.Ct. 2240 (discussing the presumption against preemption in situations implicating "federalism concerns and the historic primacy of state regulation of matters of health and safety").
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> Third, the presumption against federal preemption of a state statute designed to foster public health has special force when it appears that the two governments are pursuing "common purposes." [Pharm. Research & Mfrs. Of Am. v.] Walsh, [538 U.S. 644 (2003)] (citations omitted). . .

AWP IV, 321 F. Supp. 2d at 197-98.

Here, the second and third factors identified by this Court clearly favor invocation of the presumption against preemption. The state laws Plaintiffs seek to enforce–laws prohibiting

[19] *AWP IV* synthesized the Court's preemption analysis from two earlier decisions in the Average Wholesale Price litigation, *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, 263 F. Supp. 2d. 172, 186-92 (D. Mass. 2003) ("*AWP I*") and *In Re Pharmaceutical Industry Average Wholesale Price Litigation*, 309 F. Supp. 2d 165, 171-77 (D. Mass. 2004) ("*AWP III*").

unfair and deceptive business practices and fraud–are fields which states have traditionally had principal responsibility for regulating. Defendants assert that the states have little interest or experience in regulating off-label promotion of pharmaceuticals, but such comments deliberately mischaracterize Plaintiffs' claims.[20] Plaintiffs seek to enforce the fundamental rights of the states to curb abusive and deceptive business practices, an area where Courts will not find preemption unless Congress' purpose was "clear and manifest." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 172, 145-47 (1973) (where state law was designed to prevent the deception of consumers, Court cannot find that Congress intended to preempt such laws "in the absence of an unambiguous congressional mandate to that effect.")

Further, although the Court does not have a Medicaid statute in front of it, which may be the paradigm of a federal statutory scheme intended to be jointly enforced by federal and state regulation, the federal and state anti-fraud laws both pursue a common purpose–to insure the communication of complete and accurate information regarding prescription drugs. Indeed, the FDCA explicitly contemplates that state regulation of drug marketing practices will parallel and assist federal regulation. 21 U.S.C. § 333(b), the section of the FDCA which sets forth the

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[20] In *Lupron®*, 295 F. Supp. 2d at 178, Judge Stearns recognized, and rejected, a similar mischaracterization by a pharmaceutical company that argued that plaintiffs' consumer protection claims in connection with an overbilling fraud were preempted.

> Plaintiffs are not seeking, as defendants claim, a judicial declaration invalidating the use of the Lupron® and other AWPs (average wholesale prices) by Medicare regulators as a benchmark for setting reimbursement rates for prescription drugs. What plaintiffs are instead seeking is to punish defendants for fraudulently manipulating the spread between the AWP and the actual cost of the drug and for encouraging doctors to falsely bill for free samples as part of a scheme to promote brand loyalty, ultimately at plaintiffs' expense.

When the plaintiffs' claims were viewed from the proper perspective, the Court found that the consumer protection claims had not been preempted by Congress. *Id.* at 179. Judge Stearns' analysis is not unique. As noted in Plaintiffs' original opposition, at p. 31, n. 39, analogous preemption claims are routinely asserted by pharmaceutical companies and almost universally rejected.

penalties for "prescription drug marketing violations", expressly federalizes violations of state law regulations relating to prescription drug marketing." Similarly, 21 U.S.C. § 335(b)(2)(A) permits the Secretary of HHS to debar drug manufacturers and others for certain violations of state laws relating to prescription drugs. While neither of these statutes directly references the specific state laws Plaintiffs seek to enforce in this action, the very text of the FDCA shows that Congress never intended exclusive federal regulation of prescription drug marketing practices, but recognized that both state and federal law should regulate in this arena.

Thus, the only reason that the presumption against preemption would not apply was if Plaintiffs' claims were premised on a "fraud on the agency" theory. *Cf. Nathan Kimmel, Inc. v. DowElanco*, 275 F.3d 1199, 1205 (9th Cir. 2002) (claim based upon alleged provision of false information to EPA in connection with labeling change was pre-empted). No such theory is found in Plaintiffs' complaints. Plaintiffs do not allege that the FDA was duped or misled; at most they allege that the FDA was circumvented. Yet even that conduct, by itself, is not the core of the wrongs alleged in the Complaints. Instead, Plaintiffs allege that Defendants misled the public (and the Plaintiffs) regarding the effectiveness of Neurontin for unapproved uses. Plaintiffs' damages arise because they, not a federal agency,[21] were misled.

Taking a sentence from *Buckman Company v. Plaintiffs' Legal Committee*, 531 U.S. 341, 353 (2001) out of context, Defendants urge that the presumption against preemption in inapplicable whenever a federal enactment is a "critical element" in the plaintiff's case.[22]

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[21] The significance of this distinction is apparent in one of the cases cited by Defendants in their reply memorandum, *Webster v. Pacesetter, Inc.*, 259 F. Supp. 2d 27, 38-39 (D. D.C. 2003). There, the Court recognized that the plaintiffs' fraud claim based on the manufacturer's failure to report certain information to the FDA was preempted. The Court, however, did not find that plaintiff's claim that the manufacturer had misled the plaintiff was pre-empted. Although that claim ultimately failed for lack of evidence, the Court allowed it to be litigated on the merits.

[22] If one were to attempt to condense the holding of *Buckman* to its essence, it would not be that

Defendants wildly overstate *Buckman*'s scope. As this Court recognized in *AWP I, Buckman* does not apply when the "the decision of the pharmaceutical companies, not an agency action, is alleged to cause the plaintiffs' harm." 263 F. Supp. 2d at 189 (citing *Green v. Fund Asset Management, L.P.*, 245 F.3d 214, 233 (3d Cir. 2001) and *Caraker v. Sandoz Pharmaceuticals Corp.*, 172 F. Supp. 2d 1018, 1039 (S.D. Ill. 2001)); *see also In re Lupron Marketing and Sales Practices Litig.*, 295 F. Supp. 2d 148, 179, n.33 (D. Mass. 2003) (finding *Buckman* largely irrelevant because although defendants submitted the allegedly fraudulent data to the government, they unilaterally established fraudulently inflated prices and such prices were not subject to regulatory approval). Here, the promotional materials and events which are alleged to have been misleading were not preapproved by the FDA and the content of such material was within the control of Defendants. As in *AWP* and *Lupron*, *Buckman* simply does not apply.[23]

Once the presumption against preemption attaches, Defendants must show that there is an "actual conflict" between the state claims and the federal statute and that any impediment is "severe." *AWP IV*, 321 F. Supp. 2d at 199. Defendants point to no conflict between the anti-

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preemption is appropriate whenever a federal enactment is "critical" to a plaintiff's cause of action, but that preemption only applies when a plaintiff's fraud claim exists solely because of a federal statute that requires disclosure of information for the exclusive use of a federal agency. *See* 531 U.S. at 352-53 (preemption does not arise when "claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not *solely* by virtue of the FDCA disclosure requirements. In the present case, however, the fraud claims exist *solely* by virtue of the FDCA disclosure requirements." (emphasis added) (citations omitted)).

As described above, here Plaintiffs' state law claims do not arise solely due to Defendants' failure to comply with the FDA's off-label promotion regulations, but due to Defendants' use of deceptive marketing practices to promote Neurontin.

[23] In those circumstances where the plaintiff's claim depends upon proof that the defendants' misconduct resulted in the "wrong" regulatory action, the concerns about undermining the regulatory scheme expressed by the Supreme Court in *Buckman*–second guessing the regulating body and overburdening the applicant because state law may require more onerous disclosures than the regulating body–are palpable. However, in cases such as this, where the allegation is that Defendants developed a complex scheme to *avoid* subjecting themselves to regulatory scrutiny, no such concerns are present.

fraud provisions of the FDCA and the state law causes of action brought by the Plaintiffs.[24] The fact that the FDCA does not provide a private right of action is hardly a substantive conflict between the requirements of state and federal law. As the Supreme Court recently noted, ordinarily, state common law actions that enforce federal substantive requirements reinforce and aid the attainment of those statutory objectives. *Bates v. Dow Agrosciences LLC*, ___ U.S. ____, 125 S.Ct. 1788, 1802 (2005) ("Private remedies the enforce federal misbranding requirements would seem to aid, rather than hinder the functioning of [such statutes]").

Indeed, the fact that Congress failed to provide a private right of action to enforce a statute clearly designed to protect the citizenry is strong evidence that Congress did not intend to preempt common law claims based upon violations of those requirements. *Id.* at 1801 ("If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly"); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) ("It is difficult to believe Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct.").

Defendants also claim potential conflicts with the federal statute might arise because juries might reach different conclusions than the FDA regarding the requirements imposed on drug manufacturers. These theoretical musings do not constitute "actual conflicts," and are insufficient to overcome the presumption, particularly where Congress has not seen fit to include an express preemption provision in the statute. Moreover, the Supreme Court recently rejected this same precise argument in *Bates*.[25]

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[24] Nor do Defendants identify any difference between the FDA's rules against off-label promotion by drug companies and any state law regulation of off-label promotion.

[25] "While it is true that properly instructed juries might on occasion reach contrary conclusions on a similar issue of misbranding, there is no reason to think that such occurrences would be frequent or that they would result in difficulties beyond those regularly experienced by

Defendants wrongly assert that no cases permit plaintiffs to use state and common law claims to recover for violations of federal regulations or statutes that may be enforced only by the federal government. Reply Br. at 32. In fact, the Supreme Court authorized such actions in *Bates* and *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996). In *Bates*, plaintiffs brought a common law action for fraud against a pesticide manufacturer which allegedly failed to comply with federal labeling requirements imposed by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), a statute that contains no private right of action. Plaintiffs' cause of action was wholly dependent upon defendants' failure to provide accurate labeling under the federal act, and the statute contains an express preemption provision prohibiting states from establishing "requirements" in addition to or different from the obligations imposed by FIFRA. Yet, despite a statutory scheme that gave primary enforcement responsibility to the EPA, the Supreme Court held that the state could create private rights of action for violations of the statute, as long as no different or additional substantive requirements were imposed on the manufacturers. 125 S.Ct. at 1799-1801; *see also Medtronic*, 518 U.S. at 495 (states can create traditional damages remedies for violations of common law duties when those duties parallel federal requirements, including failure to meet labeling requirements under the FDCA).

It is ironic that Defendants are arguing that Plaintiffs' rights are preempted by the very statute whose requirements Defendants systematically evaded. Had Defendants in fact sought FDA approval for Neurontin's off-label uses, they would have had to establish the drug's efficacy for such purposes. Had they made such a showing, Defendants would have a plausible argument that the FDA's finding of efficacy pre-empts any common law claim that Defendants misrepresented the drug's efficacy. Yet, as the Complaints allege at length, Defendants

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manufacturers of other products that everyday bear the risk of conflicting jury verdicts." 125 S.Ct. at 1803.

deliberately chose to forego the FDA process in order to increase their profits vastly. Having made a deliberate, but illegal, choice to circumvent the regulatory process, Defendants can hardly invoke the protections of the same statute they criminally violated.

IX. PLAINTIFFS' CLAIMS WERE TIMELY-FILED

Defendants' statute of limitations argument mangles both the facts and the law. Its cornerstone is the patently frivolous argument that Plaintiffs were placed on "inquiry notice" of their claims, and that the statute of limitations commenced to run, "at the time they paid for off-label uses of Neurontin," ostensibly because "plaintiffs were put on notice of their injuries when they began paying for off-label uses of Neurontin." Reply Br. at 36, 37. The only facts on which Plaintiffs were put on notice when they paid for off-label Neurontin prescriptions were that the prescriptions had been written, and the cost of filling them. In a fraud case, "inquiry notice" does not occur, and the statute of limitations does not begin to run, until "circumstances suggest to a person that he may have been *defrauded* . . . ." *Blue Cross v. SmithKline Beecham Clinical Labs, Inc.*, 108 F. Supp. 2d 116, 122 (D. Conn. 2000) (emphasis added).[26] The mere prescription and purchase of Neurontin for off-label uses did nothing to alert Plaintiffs to the existence of a fraud.

Nor are citizens under a legal duty to continuously scan every publication in the English language, looking for shards of evidence that they may have been defrauded. Rather, potential plaintiffs are not placed on "inquiry notice" of their claims, imposing on them a duty to inquire further, unless and until information sufficient to suggest that they may have been defrauded has become so "highly publicized" that a reasonable person would have been aware of it.

[26] *Epstein v. C.R. Bard, Inc.*, No. CIV.A.03-12297, 2004 WL 1598912, (D. Mass. July 19, 2004), cited by Defendants, makes the analogous point that "[n]otice here refers . . . to discovery of the plaintiff's injury *as causally connected to the defendant's negligence*." *Id.* at *2 (emphasis added).

Defendants openly concede this point.[27]

Defendants do not dispute that the negligible publicity to which they point is insufficient to satisfy this test -- the unsealing of the *Franklin* complaint, which received no publicity whatsoever; a cryptic statement in an SEC filing that the U.S. Attorney was investigating Warner-Lambert's "promotion of NEURONTIN"; a single, 225-word article on page B-16 of the *Wall Street Journal*, in the Health Section, which merely noted the SEC filing, and stated that the investigation concerned marketing for unapproved uses; and a single article in "The Pink Sheet," an obscure trade publication, which revealed no additional relevant information except Neurontin sales figures. As Plaintiffs argued in their opposition, the question of whether these unpublicized events and obscure articles were sufficient to place Plaintiffs on "inquiry notice" is "a jury issue." *Lupron*, 295 F. Supp. 2d at 183.[28] Accordingly, Defendants' motion to dismiss

[27] *See* Reply Br. at 37-38 ("Plaintiffs' contention that the alleged misconduct was not 'highly publicized' or 'industry-wide' misses the mark as a legal matter. Plaintiffs mistakenly rely on the standard for determining whether a plaintiff has been put on inquiry notice of the alleged conduct, not whether a plaintiff exercised due diligence after being put on inquiry notice of his injury. The cases that plaintiffs cite make this clear. *See Blue Cross v. SmithKline Beecham*, 108 F. Supp. 2d 116 123-24 (D. Conn. 2000) (addressing whether dissemination of information constituted inquiry notice).").

[28] As Defendants' own authorities note, complaints are rarely dismissed on statute of limitations grounds pursuant to Rule 12(b)(6). *See, e.g., Epstein*, 2004 WL 1598912, at *2 (noting that "[t]he existence of notice of causation is a factual inquiry," and relying upon plaintiff's own admission that a letter sent to him provided him with "indicia of foul play" to find the requisite notice); *Slavin v. Morgan Stanley & Co.*, 791 F. Supp. 327 (D. Mass. 1992) (stating that "[n]ormally, the exercise of reasonable diligence would be a question of fact and not amenable to summary disposition"). In *Callahan v. United States of America*, 337 F. Supp. 2d 348 (D. Mass. 2004), the third case cited by Defendants, the administratix of a murder victim's estate brought an action asserting claims arising out of a murder allegedly committed by informants of the FBI. The Plaintiff there only argued that she lacked two specific items of knowledge relevant to the accrual of her claim: the identity of her husband's murderer and the reason for which her husband was murdered. In finding that the a reasonable plaintiff would have been put on notice of these facts, the court relied upon numerous newspaper articles relating to the FBI's involvement in the murder, including an article for which the Plaintiff was interviewed and quoted.

Plaintiffs' RICO claims on statute of limitations grounds should be denied.[29]

Nor do Defendants deny that Plaintiffs have alleged, with sufficient particularity, that Defendants went to extraordinary lengths to conceal the details of their involvement in the off-label promotion of Neurontin, which was essential to the continued success of the scheme, satisfying the first requirement for invocation of the doctrine of fraudulent concealment. *See Berkson v. Del Monte Corp.*, 743 F.2d 53, 55 (1st Cir. 1984). In response, Defendants argue that despite this "self-concealing" fraud, Plaintiffs did not exercise due diligence in discovering their claims, because the facts necessary to support those claims were publicly available, in the form of the documents discussed above.

Defendants' argument is at once circular, nonsensical, and self-contradictory. Defendants argue that these materials "would have been discovered by anyone exercising even minimal diligence" (Reply Br. at 36), but they do *not* argue – in either of their briefs -- that these materials were detailed enough or well enough disseminated to place Plaintiffs on inquiry notice that they may have been defrauded, giving *rise* to any duty to investigate further.

Even if Plaintiffs *had* become aware of the U.S. Attorney's investigation, based on an SEC filing and two obscure press reports (one of which also reported that both the U.S. Attorney's office and Warner-Lambert refused to provide any additional information), it does *not* follow that Plaintiffs should have become aware of the existence of a *qui tam* complaint, filed several years earlier, which received *no press mention whatsoever* until March 14, 2002, well within the limitations period. *See* Opp. Br. at 37 n.51. It is "black letter law" that "[e]ven though a plaintiff might have inquiry notice of a potential claim, it does not follow that

[29] As Plaintiffs noted in their opposition, and Defendants do not contest, Plaintiffs could still recover under RICO any damages incurred within four years of the filing of their complaints. *See* Opp. at 39 n.51.

reasonable diligence will discover sufficient facts to support legal action. Where such is the case, the failure to file suit on the basis of such information does not necessarily show a lack of due diligence." 32 *Am. Jur. Proof of Facts 3d* 129 § 10 (2004) (citation omitted). As the First Circuit has explained:

> Once a duty to inquire is established, the plaintiff is charged with the knowledge of *what he or she would have uncovered through a reasonably diligent investigation*. The next question is whether the plaintiff, if armed with the results of that investigation, would known enough to permit a reasonable person to believe that she had been injured and that there is a causal connection between the [defendant] and her injury. . . . *This inquiry is highly fact- and case-specific,* as are the pertinent questions to ask.

McIntyre v. United States, 367 F.3d 38, 52 (1st Cir. 2004) (emphasis added). Like the question of when Plaintiffs were placed on "inquiry notice," the question of whether they exercised due diligence thereafter is a fact-intensive inquiry inappropriate for resolution on a motion to dismiss.

Finally, even if Plaintiffs were placed on inquiry notice, and even if a reasonable investigation would have turned up the unsealed and unpublicized original complaint in *Franklin*, that complaint was devoid of the factual detail Defendants urge is necessary to avoid dismissal. Defendants do not suggest how Plaintiffs could have gotten the information necessary to file a viable lawsuit, with neither Defendants nor the government willing to share this information. *See Attalah v. United States*, 955 F.2d 776, 780 (1st Cir. 1992) (reversing dismissal on statute of limitations grounds notwithstanding plaintiffs' awareness of law enforcement investigation, because "[t]he police did not have sufficient information to bring charges against the responsible Customs agents until 1987. We believe appellants could not have been more efficient.").

X. PLAINTIFFS HAVE STATED CLAIMS FOR UNJUST ENRICHMENT

Defendants advance no additional arguments concerning Plaintiffs' unjust enrichment claim not already addressed above.

XI. CONCLUSION

For the foregoing reasons, the motions to dismiss should be denied.

Respectfully submitted,

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